

Title: METHOD AND APPARATUS FOR DETERMINING EFFECTIVENESS OF
SUNSCREENS AND OTHER SKIN PREPARATIONS IN SHIELDING HUMAN SKIN
FROM UVA RADIATION

Inventor: HAYWOOD et al.

AMENDMENT TO THE CLAIMS

Please amend the claims as follows before calculating the filing fee:

1. **(Original)** A method for measuring the effectiveness of a sunscreen composition or other skin preparation in reducing the exposure of human skin to UVA radiation, the method comprising:

irradiating a sample of human skin or of an effective substitute therefor (herein: "skin"), shielded with the sunscreen composition or other skin preparation to be tested, with UV radiation comprising UVA wavelengths, and determining by electron spin resonance (ESR) spectroscopy the level of induced production of ascorbate radical in the shielded skin; and

determining a quantitative measure of the effectiveness of the sunscreen composition in reducing the exposure of human skin to UVA radiation by comparison of the said level of ascorbate radical production in the shielded skin with the level of ascorbate radical production induced in reference skin under substantially quantitatively comparable conditions.

2. **(Original)** A method according to claim 1, wherein the level of ascorbate radical production induced in reference skin under substantially quantitatively comparable conditions is measured by irradiating a sample of reference skin with UV radiation comparable to that used to irradiate the test sample, in the absence of the sunscreen composition or other skin preparation, and determining by ESR spectroscopy under ESR conditions comparable to those for the test sample the level of induced production of ascorbate radical in the reference skin.

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3. **(Original)** A method according to claim 1, wherein the level of ascorbate radical production induced in reference skin under substantially quantitatively comparable conditions is measured by irradiating a sample of reference skin, shielded using a shield having known UVA absorbing characteristics, with UV radiation comparable to that used to irradiate the test sample, and determining by ESR spectroscopy under ESR conditions comparable to those for the test sample the level of induced production of ascorbate radical in the reference skin.
4. **(Currently Amended)** A method according to ~~any one of the preceding claims~~ **claim 1**, wherein the skin sample used for the test and the reference skin sample are the same.
5. **(Currently Amended)** A method according to ~~any one of claims 1 to 3~~ **claim 1**, wherein the skin sample used for the test is different from the reference skin sample, the two samples being functionally comparable under the ESR conditions used.
6. **(Currently Amended)** A modification of a method according to ~~any one of the preceding claims~~ **claim 1**, wherein in place of, or alongside, the determination of the level of induced production of ascorbate radical in the skin there is determined by ESR spectroscopy the level of UV-induced production of one or more other measurable radical in the skin in the unshielded and shielded skin.
7. **(Currently Amended)** A method according to ~~any one of the preceding claims~~ **claim 1 or claim 6**, wherein the skin sample and the reference skin are irradiated with the UV radiation in the presence of a spin trap molecule capable of forming with the ascorbate and/or with the said one or more other radical an adduct which is

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substantially quantitatively stable over a lifetime of at least about 100s and is measureable using ESR spectroscopy.

8. **(Currently Amended)** A method according to ~~any one of the preceding claims claim 1 or claim 6~~, wherein the UV radiation is radiation having a wavelength in the range between about 4 and 400nm and the UVA radiation is UV radiation in the wavelength range 320-400nm.

9. **(Original)** Apparatus for testing the effectiveness of a sunscreen composition or other skin preparation in reducing the exposure of human skin to UVA radiation, the apparatus comprising:

at least one sample of human skin or of an effective substitute therefor (herein: "skin");

a source of UV radiation comprising UVA wavelengths;

means for determining by electron spin resonance (ESR) spectroscopy the level of induced production of ascorbate or other measureable radical in a skin sample on exposure of the skin to the UV radiation;

means for shielding a skin sample with the sunscreen composition or other skin preparation to be tested; and

means for determining a quantitative measure of the effectiveness of the sunscreen composition or other skin preparation in reducing the exposure of human skin to UVA radiation by comparison of the level of ascorbate or other measureable radical production in the shielded skin with the level of ascorbate or other measureable radical production induced in reference skin under substantially quantitatively comparable conditions.

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10. **(Original)** An apparatus according to claim 9, wherein the radical is ascorbate.

11. **(Currently Amended)** An apparatus according to claim 9 ~~or claim 10~~, wherein the UV radiation is radiation having a wavelength in the range between about 4 and 400nm and the UVA radiation is UV radiation in the wavelength range 320-400nm.

12. **(Original)** A method for assigning a UVA sun protection factor (UVASPF) or free radical protection factor (FRPF) to a sunscreen composition or other skin preparation, which method comprises measuring the effectiveness of the sunscreen composition or other skin preparation in reducing the exposure of human skin to UVA radiation, using the method of any one of claims 1 to 8 or the apparatus of claim 9 or claim 10 or claim 11, expressing the said effectiveness as the fraction (f) of unshielded UVA-induced ascorbate radical production exhibited by the shielded skin, and assigning the UVASPF or FRPF to the composition or preparation by virtue of the relationship:

$$\text{UVASPF or FRPF} = 1/f.$$

13. **(Currently Amended)** A sunscreen composition or other skin preparation ~~comprising, to which~~ a UVASPF or FRPF that has been assigned according to the method of claim 12.

14. **(Original)** A sunscreen composition or other skin preparation according to claim 13, preferably for application to the skin at least once per day, wherein the assigned UVASPF or FRPF is above the safe minimum UVASPF or FRPF for the latitude, season and/or climate in which the composition or preparation is to be used, calculated having

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regard to a safe maximum daily exposure to UVA radiation and an assumed, expected or likely actual daily exposure to UVA radiation at that latitude, season and/or climate.

15. **(Currently Amended)** ~~Use of differential ESR spectroscopy in a~~ **A** method for measuring the effectiveness of a sunscreen composition or other skin preparation in reducing the exposure of human skin to UVA radiation **comprising the step of using differential ESR spectroscopy to determine an induced ascorbate radical production level.**

16. **(Currently Amended)** The **use method** according to claim 15, wherein the differential ESR spectroscopy is used to quantify UVA-induced ascorbate radical production in skin shielded by the said composition or other skin preparation, in comparison with reference, preferably unshielded, skin.

17. **(Currently Amended)** The **use method** according to claim 15 ~~or claim 16~~, wherein the UVA radiation is UV radiation in the wavelength range 320-400nm.

Respectfully submitted,



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